

Notice of Agency Rule-making Proposal

AGENCY: 02-373 Board of Licensure in Medicine; 02-392 Board of Pharmacy

CHAPTER NUMBER AND TITLE: Chapter 5 (Board of Licensure in Medicine) and Chapter 39 (Board of Pharmacy): Collaborative Drug Therapy Management (new joint rule for both boards)

PROPOSED RULE NUMBER (leave blank; assigned by Secretary of State):

CONTACT PERSON FOR THIS FILING: Geraldine Betts, Board Administrator, Board of Pharmacy, 35 State House Station, Augusta, ME 04333, tel. (207) 624-8625; Dennis Smith, Executive Director, Board of Licensure in Medicine, 137 State House Station, Augusta, ME 04333, tel. (207) 287-3601

CONTACT PERSON FOR SMALL BUSINESS INFORMATION (if different): Same as above.

PUBLIC HEARING (if any): None Scheduled.

COMMENT DEADLINE: January 4, 2016 at 5pm.

BRIEF *SUMMARY: The Board of Licensure in Medicine and the Board of Pharmacy propose a new joint rule relating to collaborative drug therapy management, as established by collaborative practice agreements between practitioners and pharmacists. A more detailed description and the text of the proposed rule may be obtained from www.maine.gov/professionallicensing.

IMPACT ON MUNICIPALITIES OR COUNTIES (if any): None.

STATUTORY AUTHORITY FOR THIS RULE: 32 MRS §§ 13720, 13846 (Board of Pharmacy); 32 MRS § 3269(3), (7) (Board of Licensure in Medicine)

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different):

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: holly.doherty@maine.gov

* Check one of the following two boxes.

☒ The above summary is for use in both the newspaper and website notices.

☐ The above summary is for the newspaper notice only. A more detailed summary / basis statement is attached.

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT _____ DATE: _____
(authorized signature)

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
Split cost equally among the following two licensing boards:						

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

**373 BOARD OF LICENSURE
IN MEDICINE
Chapter 5**

**392 MAINE BOARD OF
PHARMACY
Chapter 39**

COLLABORATIVE DRUG THERAPY MANAGEMENT

Summary: This is a joint rule of the Board of Licensure in Medicine and the Board of Pharmacy for purposes of establishing safe and effective collaborative practice agreements, treatment protocols, and documentation and reporting requirements between a pharmacist and a practitioner.

Acknowledgment. The Boards recognize that the Maine Legislature enacted 2013 Public Law Chapter 308 to allow collaborative practice agreements between authorized practitioners and pharmacists and to expand access to healthcare while ensuring that all patients receive the most appropriate healthcare possible and to provide safe and efficient care to the citizens of Maine.

1. Definitions

1. **Board.** For purposes of this chapter, “Board” means the Maine Board of Pharmacy.
2. **Collaborative drug therapy management.** “Collaborative drug therapy management” is defined in 32 MRS § 13702-A(2-A). The statutory requirements for collaborative drug therapy management are set forth in 32 MRS §§ 13841-13847.
3. **Collaborative practice agreement.** “Collaborative practice agreement” is defined in 32 MRS § 13702-A(2-B).
4. **Practitioner.** “Practitioner” is defined in 32 MRS § 13702-A(29).
5. **Qualifying condition.** “Qualifying condition” means a condition or disease with generally accepted standards of care, which may include the following examples:
 - A. Anticoagulation
 - B. Asthma
 - C. Diabetes
 - D. Dyslipidemia

- E. Hyperlipidemia
 - F. Hypertension
 - G. Infectious Disease
 - H. Cancer
 - I. Thyroid Disorder
6. **Treatment protocol.** “Treatment protocol,” as referenced in 32 MRS § 13845, means the written document by which the practitioner describes the activities of drug therapy management in which the pharmacist is authorized to engage under a collaborative practice agreement and specifies the procedures and parameters of that practice authority.
7. **Unrestricted pharmacist license.** “Unrestricted pharmacist license” means a pharmacist license, the holder of which is not subject to any conditions of licensure affecting the scope of practice.

2. Application

1. Pharmacist Qualifications

In order to enter into a collaborative practice agreement with a practitioner, a pharmacist must meet the qualifications set forth in 32 MRS § 13842. The pharmacist must complete the 15 hours of continuing education referred to in 32 MRS § 13842(2)(A), (B), and (C) within the two-year period preceding the date of application.

[Note: A pharmacist who enters into a collaborative practice agreement must agree to complete, in each year of the agreement, continuing education hours as set forth in 32 MRS § 13735.]

2. Application Submission

The pharmacist shall submit to the Board an application form supplied by the Board and such other information as the Board may require. Incomplete applications will not be considered and will be returned to the applicant.

3. Collaborative Practice Agreement Submission

Prior to commencement of the collaborative practice, the pharmacist shall submit to both the Board and the licensing board that licenses the practitioner a copy of the collaborative practice agreement. A copy of the treatment protocol, as established by the practitioner, must be included in the submission.

3. Collaborative Practice Agreement Content

A collaborative practice agreement may authorize collaborative drug therapy management only for qualifying conditions. A collaborative practice agreement must:

1. Require that activity in the initial 3 months of a collaborative practice agreement be limited to monitoring drug therapy, after which, the practitioner and pharmacist shall meet to review the collaborative practice agreement and determine the scope of the agreement, which, only after this meeting, may be expanded to include a pharmacist's initiating, monitoring, modifying, and discontinuing a patient's drug therapy, which actions the pharmacist must report to the practitioner in a timely manner;
2. Identify the parties to the agreement and their dates of execution of the agreement, and specify the effective date and expiration date of the agreement;
3. Permit either party to cancel the collaborative practice agreement by written notification;
4. Specify the site and setting at which the collaborative practice will occur;
5. Specify the qualifications of the participants in the collaborative practice agreement;
6. Describe in detail the types of diseases, drugs or drug categories involved and collaborative drug therapy management allowed in each patient's case;
7. Include a procedure for the referral of each patient to the practitioner that expressly states:
 - A. No party to the collaborative practice agreement may receive remuneration of any kind for a referral made pursuant to the agreement; and
 - B. The practitioner is under no obligation to refer patients to the contracting pharmacist;
8. Include a plan for measuring and assessing patient outcomes;
9. Require that all parties to the agreement maintain professional liability insurance covering the scope of the collaborative practice, which proof of insurance shall be attached to the agreement;
10. Include the treatment protocol(s) that will be utilized under the agreement;

11. Contain a provision that states that the agreement will terminate immediately in the event that the pharmacist no longer holds an unrestricted pharmacist license;
12. Contain a provision that states that the agreement will terminate upon the death of a party to the agreement; and
13. Specify how the continuity of care for patients will be handled in the event that the agreement suddenly terminates.

Subsections 1 - 9 above are the minimum requirements set forth in 32 MRS § 13843(5) and (6).

4. Treatment Protocol Content

A treatment protocol shall describe the activities that the pharmacist is authorized to engage in and must, at a minimum, include the requirements set forth below.

1. **Informed Consent Procedures.** The protocol shall specify the procedures for obtaining informed consent from each patient involved in the drug therapy management, which consent shall include the patients' consent to release all relevant medical information to both the practitioner and the pharmacist.
2. **Scope of Activities.** A description of the activities the pharmacist is authorized to engage in, including the procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management pursuant to a medical order from the practitioner.
3. **Documentation.** A description of the manner in which the pharmacist shall document all activities involved in providing drug therapy management in collaboration with a practitioner.
4. **Communication.** A description of the procedures the pharmacist shall follow for reporting activities and results to the practitioner, including but not limited to:
 - A. A description of the timeframe in which the pharmacist must relay normal test results to the practitioner, not to exceed one week for routine results and twenty-four hours for abnormal results; and
 - B. A description of the timeframe in which the pharmacist must relay adverse drug events, not to exceed twenty-four hours.
5. **Supervision.**
 - A. A provision that allows the practitioner to override a collaborative practice decision made by the pharmacist when appropriate; and

- B. A provision that provides for periodic review and revision of the drug therapy management by the practitioner and pharmacist.

5. Notifications

A pharmacist shall notify both the Board and the board that licenses the practitioner of the occurrence of any of the following changes no later than 10 days after the change:

1. Any modification to a collaborative practice agreement, which notification must include a copy of the amended collaborative practice agreement, which must be signed and dated in accordance with section 3(2) of this rule;
2. Any modification to a treatment protocol, which notification must include a copy of the amended treatment protocol; and
3. Any change in liability insurance, which notification must include proof of existing liability insurance, i.e., a liability insurance policy certificate.

6. Recordkeeping Requirements

Records received or created by a pharmacist pursuant to this chapter are subject to the record retention and production requirements of Chapter 24 of the Board's rules.

7. Complaints

In the event that the Board or the licensing board that licenses the practitioner receives a complaint related to a collaborative practice agreement, the boards may share the complaint and any investigative information obtained during an investigation of the complaint, as permitted under 10 MRS § 8003-B(2).

8. Duty to Report Disciplinary Action

1. Any party to a collaborative practice agreement who has had disciplinary action taken against any professional license held by that party shall report such disciplinary action to all other parties to the agreement and to the licensing boards of those parties within 10 days of the disciplinary action.
2. The Board and the Board of Licensure in Medicine shall notify each other of any disciplinary action against the professional licensees who are party to a collaborative practice agreement as soon as practicable.

STATUTORY AUTHORITY:

32 MRS §§ 13720, 13846 (Board of Pharmacy)

32 MRS § 3269(3), (7) (Board of Licensure in Medicine)

EFFECTIVE DATE:

Rule-Making Fact Sheet

(5 MRS § 8057-A)

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STATUTORY AUTHORITY: 32 MRS §§ 13720, 13846 (Board of Pharmacy); 32 MRS § 3269(3), (7) (Board of Licensure in Medicine)

DATE AND PLACE OF PUBLIC HEARING: None Scheduled.

COMMENT DEADLINE: January 4, 2016 at 5pm.

PRINCIPAL REASON OR PURPOSE FOR PROPOSING THIS RULE: To set forth rules authorized by PL 2013, c. 308, "An Act to Allow Collaborative Practice Agreements between Authorized Practitioners and Pharmacists."

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (PRIMARY SOURCES): Professional judgment of the boards; research conducted on the types of collaborative practice agreements authorized in other jurisdictions; consideration of the work already being done by pharmacists pursuant to agreements with hospitals for the treatment of hospital inpatients (such agreements are exempted from the statute and implementing rules by 32 MRS § 13847); and review of comments received from consultation with the Department of Health and Human Services.

ANALYSIS AND EXPECTED OPERATION OF THE RULE: This is a consolidated rulemaking proceeding of the Board of Licensure in Medicine and the Board of Pharmacy to adopt a new joint rule relating to collaborative drug therapy management, as established by collaborative practice agreements between practitioners and pharmacists. The proposed joint rule implements PL 2013, c. 308, which directed the Board of Pharmacy and the Board of Licensure in Medicine, after consultation with the Department of Health and Human Services, to adopt rules.

The proposed joint rule defines terms, sets forth the application process, outlines the minimum content required in a collaborative practice agreement and treatment protocol, and sets forth provisions on recordkeeping, complaints, and reporting to the boards.

FINDINGS UNDER CRITERIA CONTAINED IN EXECUTIVE ORDER 20 FY 11/12:

(A) The proposed rule will not negatively impact job growth or creation; (B) There are no fees

included in the rule; (C) There is no cost to the public in terms of time and money required to comply with the rule; (D) No other state laws or rules already address the subject matter of this rule; (E) There are no relevant federal standards.

FISCAL IMPACT OF THE RULE: None.

FOR RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:

INDIVIDUALS OR GROUPS AFFECTED AND HOW THEY WILL BE AFFECTED:

BENEFITS OF THE RULE:

Note: If necessary, additional pages may be used.